

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

Plaintiffs	Defendants
UNITED STATES OF AMERICA vs. JOHN SHER & THOMAS SHER, et. al.	Criminal No: 19-191-RBK

**MEMORANDUM IN SUPPORT OF OMNIBUS PRETRIAL MOTION
OF DEFENDANTS JOHN SHER AND THOMAS SHER TO DISMISS INDICTMENT;
BAR GOVERNMENT EXPERT TESTIMONY AT TRIAL AND TO JOIN MOTIONS
FILED OF CODEFENDANTS**

I. MOTION TO DIMSISS INDICTMENT

A. INTRODUCTION:

Defendants, John Sher and Thomas Sher (“Defendants” or “the Sher Defendants” herein), respectfully move the Court to dismiss the indictment as improperly including lawful conduct within its breath and scope and thus improperly charging the Sher Defendants , and other co- Defendants similarly situated, with healthcare fraud, wire fraud and conspiracy during the period set forth in the Indictment of July, 2014 to April, 2016 . The Sher Defendants submit that the indictment is fatally flawed as to them because it criminalizes accepted practices of medical marketing and promotions compensated by commissions paid by medical companies to sales representatives working on their behalf.

The indictment is likewise flawed as to the Sher Defendants as the Government failed to present expert testimony to the grand jury on the issue of “medical necessity” which is the linchpin of this prosecution as to the five (5) patients the Government attributes to John Sher,

and the five (5) patients it attributes to Thomas Sher. Defendant Thomas Sher further seeks to dismiss Count 21 charging receipt of a prescription from a co-Defendant as an act in furtherance of the conspiracy. Evidence was made known to the Government pre-indictment that this prescription to Thomas Sher was sent without his authorization and was immediately rejected.

Finally, Defendants seek dismissal of the indictment as the Government failed to present evidence to the grand jury that the funds paid to the Sher Defendants were anything more than lawful commissions paid to any medical sales representative and are thus not violative of the Health Care Act. No funds were directly paid to the Sher Defendants by any state health care plan. Instead, all funds were paid to the private party pharmacy administrator, Express Scripts, which currently promotes itself as a medical/pharmaceutical administrator with over 100 Million members, 27,000 employees and has saved its insurer-partners over \$50 Billion.¹

The sole function of Express Scripts as Plan Administrator was to screen prescriptions requested by insured members for the health plan. As Plan Administrator it paid the private pharmacy, Central Rexall Drugs (“Rexall” which was established over a century ago in 1896). Rexall then paid commissions to a private medical sales company. The private medical sales company then paid other independent salespersons or companies, one of which paid the Sher Defendants. None of the Defendants set price of the prescriptions sold. Rexall set all prices for the compounding pharmaceuticals it was marketing. Clearly, garden-variety pharmaceutical marketing is not illegal and no credible evidence exists that the Sher Defendants engaged in anything but lawful medical marketing activities.

For these reasons, the Indictment must be dismissed as to the Sher Defendants.

¹ <https://www.express-scripts.com/corporate/about>

B. STATEMENT OF FACTS:

On March 13, 2019, a grand jury in the District of New Jersey handed down an indictment of Defendants, including Defendant, Thomas Sher and John Sher charging conspiracy to commit health care fraud and wire fraud in violation of 18 U.S.C. 1349 and 18:1347. The Government's theory of prosecution is that the Defendants conspired to knowingly submit false prescriptions to a state health care benefit program through interstate commerce by wire which prescriptions were knowingly and willfully false. In particular, the Government alleges that the conspirators submitted false and fraudulent insurance claims for compounded prescription medications to the pharmacy benefits administrator which in turn paid a compounding pharmacy for the compounded prescriptions. The compounding pharmacy, in turn, would pay commissions to a medical sales company from the proceeds it received from the pharmacy benefits administrator. The pharmacy then paid advertisers, promoters and sales companies which paid their representatives. This activity occurs every minute of every hour of the day across the country and is not criminal conduct.

The Government does not allege any wrongdoing on the part of the compounding pharmacy, Central Rexall Drugs. The Government likewise does not allege any wrongdoing on the part of the pharmacy benefits administrator, Express Scripts. Instead, though not stated in the indictment, the Government will likely contend that the pharmacy and the administrator were lawfully compensated for those prescriptions supported by medical necessity and were allegedly misled to the extent any prescription was allegedly obtained through forgery of a physician's signature or bribery of the physician. The fact that lawful sales activity is described by the Government as a scheme does not make it unlawful. Medication commercials fill the airways every day promoting one medication over another. No doubt many state and county workers

covered under the health plans in the present case saw commercials, obtained prescription from their doctor, submitted the prescriptions to Express Scripts for approval. The Government does not suggest that national advertising companies are committing a crime despite being paid millions of advertising dollars each year. Rexall itself created a products list and marketed it to the member insureds, independent of the Sher Defendants Sher or other co-Defendants. (Exhibit 1) The very health plan the Government views as a victim, issued (and continues to issue) periodic “wellness” promotions encouraging its members to participate in a wellness lifestyle that saves the insurer money in the long-run because its members are healthier and thus should have less health claims over time. Clearly, this has the monetary benefit to the insurer of lower claims and to the plan members of lower premiums.

Examples abound of health benefit plans paying patients to get treatment or procedures at certain medical facilities or offices. Some local New Jersey examples are the SHBP and SEHBP which endeavors to increase overall wellness by financially rewarding employees and their spouses or partners for completing activities designed to promote healthy behaviors; the NJ Well Program which encourages members to take ownership of their health; and the BCBSNJ's fitness incentive program which provides a \$20 reward each month in which a member makes 12 gym visits. Yet, somehow the Government alleges it is a crime if a small unknown medical company and independent sales reps, such as the Defendants, do the same thing by word of mouth promotion.

The Government certainly has a basis to prosecute those who falsify a prescription, either by forgery or payments to a physician, to write the prescription without any medical basis. But the Government has no evidence that the Sher Defendants engaged in such conduct or had prior knowledge that others were in engaged in such wrongful conduct. Likewise, the Government

has no evidence the prescriptions to the ten persons attributed to the Sher Defendants lacked medical necessity. The volumes of discovery received fail to identify any expert for the Government who offers such evidence. Given the lack of any direct or circumstantial evidence that the Sher Defendants knowingly and willfully falsified prescriptions or paid a doctor to write a prescription, or knowingly and willfully acted with other to do so, the indictment must be dismissed for failing to charge them with a crime.

The Government contends in the indictment that the pharmacy, program administrator and the health plan were somehow misled repeatedly in that the Defendants allegedly obtained prescriptions on behalf of certain insureds (identified by number in the indictment) “*even though the individuals had no medical necessity determined by a doctor for the compounded medication.*” (emphasis added; ECF 1 at Page 9, Paragraph 14.) The Government further contends that the Defendants “*would specifically select the medications... that had the highest possible reimbursement without any determination of the medical necessity of the medications selected.*” (ECF 1, Page 9, Paragraph 15). The best that can be gleaned from the indictment is that individuals 17, 18, 19, 20, 21, 22, 23, 24, 25, 26 and 27, presumably received prescriptions without medical necessity. The indictment does not allege that these individuals did not apply for the prescriptions or use the prescriptions or claim that the prescriptions were not issued by a physician. The obvious question is what competent evidence was offered to the grand jury that these prescriptions were issued without medical necessity, and that moving Defendant knew it?

The Government wrongfully contends and presented no evidence that the Sher Defendants “*marked (the prescription forms) to request 12 months of refills in order to obtain the highest possible reimbursement, without any determination of the medical necessity of receiving the medications for 12 months.*” The Government also contends and presented no

evidence that the Sher Defendants “*would persuade individuals to agree to obtain compounded prescription medications... without any evaluation or determination by a medical professional that the individuals had a medical necessity for the compounded prescription medications.*” (ECF 1, Page 8, Paragraph 13). The Government also alleges that if the benefits administrator stopped covering a particular compounded medication, the Defendants (including by implication the Sher defendants) would allegedly complete a new prescription form without consulting with the patient, without the patients being examined by a doctor, and/or without any determination of medical necessity for the patient. (ECF 1, Page 10, Paragraph 21). No evidence exists as to the Sher defendants to support this contention.

The Government paints the picture of ten (10) clients who all went to one doctor between Thomas Sher and John Sher. In reality the discovery relating to the Sher Defendants sets forth unequivocally that the Sher Defendants had a total of 34 clients who saw thirteen doctors and one nurse practitioner among them who prescribed the compound medications obtained. Only one doctor has been accused of wrongdoing by the Government of the thirteen. Despite the Government’s contention adopted by the grand jury that every prescription was maxed out in quantity and quality of medications, in fact the evidence in the Government’s possession as to the Sher Defendants rebuts this allegation. Nearly half of the Sher Defendants’ clients were prescribed by their doctors, not the Sher defendants, the lesser of the two approved metabolic supplements (aka the multi-vitamins)

The Government has not identified any expert testimony that was offered to the grand jury to support the alleged lack of medical necessity the Government sets forth as the foundation of this prosecution. How could a grand juror know what is medically necessary as to compounded medications, prescription multi-vitamins, scar cream and libido cream., especially

after the plan administrator, a national company specializing in vetting prescriptions, reviewed and approved every prescription. With this patent lack of evidence of culpability on the part of the Sher defendants, the motion to dismiss the indictment should be granted.

III. LEGAL ARGUMENT:

A. The Sher Defendants committed no crimes and the indictment should be dismissed.

Federal Rule of Criminal Procedure 12 (A)(v) and (B) (iii) and (v) contemplates dismissal of an indictment for irregularity in the proofs to the grand jury, lack of specificity and failure to state an offense. The Sher Defendants move to dismiss the Indictment as to them due to irregularity in the lack of expert testimony to prove the element “medical necessity”; the failure to state an offense as to the Sher Defendants and the lack of an offense as to Count 21 relating to Defendant Thomas Sher.

The discovery in this case consists of over 500,000 pages. Barely a few hundred pages relate to the Sher Defendants 34 clients, many of whom are well known and respected public figures who became clients of the Sher Defendants as personal trainers and advisors. These clients collectively consulted with 13 different doctors for their prescriptions. The prescriptions were pre-advertised by and the prices set by Central Rexall, not by any Defendant. Express Scripts vetted and approved the prescriptions. An entire industry of medical auditing exists which retroactively reviews medical services provided and if over-billing or over-utilization is found, a recipient of insurance funds is directed to reimburse that portion of payments for any alleged over-billion of over-utilization. The civil remedies which are afforded major medical

providers were denied to these Defendants when their conduct was as legal as every other medical marketer in the country. For these reasons, the indictment must be dismissed.

B. The Government failed to prove medical necessity to the grand jury rendering the indictment defective

The Federal Criminal Code provides that the Healthcare Fraud Act is violated when a Defendant knowingly and willfully attempts to execute, a scheme or artifice to defraud any health care benefit program or (2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items, or services...”. 18 U.S.C. 1347(a)(1)(2) (emphasis added)

The present case is not a typical healthcare fraud action brought against medical providers for upcoding or phantom billing. Instead, the Government repeatedly and specifically alleges that prescriptions were issued to member insureds “without medical necessity.” The issue of medical necessity of issuance of prescriptions, particularly compounded prescriptions for vitamins, scar cream, weight loss medications and libido cream, are clearly beyond the common knowledge of a grand juror or juror. What is the standard for issuing a compounded medication? What role does a plan administrator play in the review process of approving the medication? Can a physician issue a prescription for a patient previously seen for routine visits without seeing that patient for that particular visit when the prescription is issued? What is the medical necessity of issuing prescription vitamins? What is the medical necessity of issuing scar cream? Must the scar cream cure the scar? Is a medical prescription appropriate when a scar is not publicly visible such as a cesarean section scar?

As to individuals 17, 18, 19, 20, 21, 22, 23, 24, 25, 26 and 27, was not expert testimony necessary to support the Government's contention that their prescriptions were issued without medical necessity? And isn't expert testimony necessary to explain the gatekeeper role of the program administrator in approving the prescriptions for payment by the health care plan?

Substantial authority exists in Courts of Appeal across the country that expert testimony is required to prove healthcare fraud where a technical issue of medical care or a medical standard such as "medical necessity" is a material element of a crime.

The United States Supreme Court in *United States v. Moore*, 423 U.S. 122, 96 S. CT. 335, 46 L.Ed.2d 333 (1975) noted that terms such as "professional practice" and "usual course of professional practice" are appropriately measured by an objective standard. In *United States v. Smith*, 573 F.3d 639 (Eighth CIR, 2009), the Eighth Circuit held that "Federal Rule of Evidence 702 permits a district court to allow the testimony of a witness whose knowledge, skill, training, experience or education will assist a trier of fact in understanding the evidence or to determine the fact in issue" citing *United States v. Kirkie*, 271 F.3d 761, 765 (Eighth CIR, 2001). District Courts have admitted "testimony tying standards of care to the existence of a legitimate medical purpose to write a prescription." *United States v. Katz*, 445 F.3d 1023 (Eighth CIR, 2006).

In affirming the conviction of a doctor in the treatment of narcotic addiction in 1975, the United States Supreme Court, addressing the potential for overbreadth in prosecuting healthcare fraud, pointed to Congressional Legislation empowering the Secretary of Health, Education and Welfare, in consultation with the Attorney General and National Addiction Treatment Organizations, to "determine the appropriate methods of professional practice in the medical treatment of... narcotic addiction" for the purpose of removing criminal prosecutions from the realm of lay opinion and providing an objective yardstick to physicians who would then run the

risk of prosecution only if they went beyond the objectively set standards of practice. *U.S. v. Moore* at 144.

The beneficial long-term effect of the Supreme Court's directive to Congress in *Moore* has been to bolster healthcare prosecutions with expert testimony. In *U.S. v. Mermelstein*, 487 F.Supp.2nd 242 (E.D.N.Y. 2007), the Government presented six expert witnesses to testify including three physicians to establish a “*physician's expertise*” in reviewing and understanding “*Defendants medical records and extract the data relevant to his testimony from them*” which the Court determined “*a lay witness would not have been able to perform this task.*” *Mermelstein* at 266. In *U.S. v. Bek*, 493 F.3d 790 (Seventh Circuit, 2017), the Seventh Circuit reversed the conviction of one doctor Defendant when no expert testimony was offered to establish a violation of the “*normal course of professional practice*” as to that doctor.

It is clear therefore that the Government ‘s singular theory of fraud is that the prescriptions all lacked medical necessity. The medical standard of what constitutes “medical necessity” in the context of this case should therefore have been presented to the grand jury, supported by qualified expert testimony, so that the grand jurors could properly weigh the materiality and culpability of the moving defendants’ alleged conduct of whether the Sher Defendants “**knowingly and willfully**” participated in a scheme to defraud. Since the Government offered no expert testimony as to the lack of medical necessity of the prescriptions issued to member insureds 17, 18, 19, 20, 21, 22, 23, 24, 25, 26 and 27, the Government failed to support material elements of the charges against the Sher defendants and thus the indictment must be dismissed.

C. Count 21 of the Indictment as to Defendant Thomas Sher must be dismissed

Count 21 alleges a co-Defendant caused a prescription for libido cream to be completed and sent under Thomas Sher's name. No evidence was presented to the grand jury that Thomas Sher was involved in this submission or had any prior knowledge of it other than to reject the prescription after-the-fact when received. This information was shared with the Government pre-indictment and was corroborated independently by at least one other witness interviewed by the Government. No independent acts of health care fraud, wire fraud or conspiracy are alleged against Defendant Thomas Sher as to this prescription. If the prescription was sent as a mistake, or a prank, no crime was committed by Defendant Thomas Sher and thus Count 21 must be dismissed.

II. MOTION TO LIMINE TO BAR GOVERNMENT EXPERTS AT TRIAL

The discovery in this matter consists of over 500,000 pages. No experts have been designated by the Government. With trial less than 90 days away, it would be impossible for any expert to join this case on either side, particularly for the Government. It would be an even greater challenge for the Sher Defendants to secure a rebuttal expert were the Government to elect to designate one now. The Government did not request a separate deadline provision in the Scheduling Order to designate an expert and produce expert reports and curriculum vitae of experts. Such a late designation would cause substantial prejudice to the Defendants and violate the Defendants' speedy trial rights as a delay in the proceedings would be required. For these reasons, it is respectfully requested that this Court bar the Government from presenting any expert testimony at trial.

**III. DEFENDANTS' MOTION FOR LEAVE TO JOIN MOTIONS OF
OTHER DEFENDANTS THAT PERTAIN TO DEFENDANTS
JOHN SHER AND THOMAS SHER**

A Defendant may request leave to join in the motions, pleading and other claims for relief that pertain to them. (See *United States v. Ramirez-Rivera*, 800 F.3d 1 (1st Cir. 2015))

Defendants, John Sher and Thomas Sher, respectfully request leave of this Court to join in the pre-trial motions of each co-Defendant to the extent such motions pertain to the interests of Defendant John Sher or Defendant Thomas Sher.

IV. CONCLUSION:

For the foregoing reasons, it is respectfully requested that this indictment be dismissed with prejudice as to the Defendants, John Sher and Thomas Sher; that Count 21 be dismissed as to Thomas Sher and, in the alternative, that the Government be precluded from using any expert witnesses at trial since no such expert has been identified to the Defendants.

/s/ Jerome A. Ballarotto

JEROME A. BALLAROTTO, ESQ.
NJ Bar No. 021301979
143 Whitehorse Avenue
Trenton, NJ 08610
(609) 581-8555
Attorney for Defendant John Sher

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